

REMARKS

Claims 1, 2, and 4-71 are all of the pending claims. By this amendment, all of the recitations of claim 3 have been added to independent claim 1, claim 3 has been canceled, and new dependent claim 70 has been added.

Claims 1, 20, 25, 39, 46, and 53 are independent claims.

Claim Objections

The Examiner has objected to the claims for not numbering the claims sequentially. To that end, the claim numbering has been corrected.

Further, claims 10, 27, 29, 68 and 70 are objected to because of a typographical error in the word “erithrithol”. This has been corrected to “erythritol”.

Claim Rejections Under 35 U.S.C. § 112

Claim 8, 39, 46, and 65 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

In claim 8 “one of a sugar and” has been moved to new claim 71 in order to avoid the ambiguity pointed out by the Examiner. In claims 39 and 46 the objectionable word “several” has been deleted. Claim 65 has been clarified to state that the tablet acts as a dental vehicle, corresponding to the understanding of the Examiner.

Thus, Applicant respectfully requests the Examiner to withdraw these rejections.

Claim Rejections Under 35 U.S.C. § 102 and 103

Claims 1-4, 12, 14-34, 36, 37, 39-41, 43, 44, 53, 55, 57-59, 61-64, and 67-70 are rejected under 35 U.S.C. § 102(b) as being anticipated by Beringer, et al. (U.S. Patent No. 4,139,589).

Claims 5-7, 13, 35 and 42 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Beringer, et al.

Claims 8-10 and 65-66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Beringer, et al. in view of Cherukuri, et al. (U.S. Patent No. 4,753,805).

Claims 11, 38, 45, 52 and 54 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Beringer, et al. in view of Fisher, et al. (U.S. Patent No. 4,370,350).

For the following reasons, Applicants respectfully traverse the Examiner's rejections.

Beringer

Beringer aims at providing tablets for use in medicine, which allow control of the release rate of the active ingredient in a more sophisticated manner (column 1, lines 19 to 25). With this purpose Beringer discloses tablets containing a tablet part and a chewing gum part, wherein the tablet part results in rapid release of the ingredient, and the chewing gum part releases the active ingredient more slowly (column 1, lines 38 to 45).

This general teaching is indicated in Beringer by means of several distinct embodiments. First of all, Beringer teaches the preparation of multi-layered tablets (e.g., Figure 10 and column 6, line 30 to column 7, line 7) and of multi-zone tablets (Figure 11 and lines column 7, lines 8 to 26).

With respect to the multi-layered tablets, Beringer describes the above-mentioned preparation in relation to Figure 10, which relies on a step of compressing the ingredients of each layer. As an alternative, lines 45-50 of column 4 teach another method of production of the tablets according to Figure 1 wherein a pre-cut disc of plastic mass is placed on a pressed tablet part, after which a second tablet part is produced on top of the gum disc.

While the Examples 6 to 12 of Beringer specifically describe the manner in which multi zone tablets are manufactured, there is no such detailed information given for Examples 1 to 5: These multi-layered tablets could have been made either by the compressing method of Figure 10, or by the pre-cutting method of Figure 4 and column 4.

Beringer does not disclose the formation of a gum part from a compressed mixture of a particulated gum base material and particulated tablet base material. This feature is nowhere to be found in Beringer. In the disclosure related to Figure 10, a granulated plastic mass is prepared from a homogeneous chewing gum mass (e.g. by cooling and grinding as described at line 35-45, column 6) after which it is compressed to form a plastic layer. There is no disclosure of the granulated gum being combined with tablet base granules prior to compression.

The methodology described in connection with Figure 10 of Beringer has no disclosure of a step of preparing a gum part wherein particles of particulated gum base material and particulated tablet base material are mixed and compressed.

This feature is part of the definition of the tabletted chewing gum sweet of claims 1, 25 and 39 and of the process for preparation of the tabletted chewing gum sweet of claim of claim 20. This feature of claims 1, 20, 25 and 39 is novel over Beringer.

However, there are also other reasons why Beringer leads an ordinarily skilled person away from the present claimed invention.

Throughout the disclosure of Beringer the material for the chewing gum is mentioned in the general term “plastic mass” (e.g., column 3, lines 55, 65 and 67). And all examples of Beringer employ chicle gum.

Gum base materials in the understanding of the ordinarily skilled person at the date of the present claimed invention, on the other hand, must exhibit both plastic and elastic properties.

Chicle is a natural product that usually exhibits plastic properties, but not elastic properties. A person of ordinary skills therefore concludes that the “plastic mass” as well as the chicle gum referred to in Beringer do not represent gum base materials relevant to the present claimed invention.

Present claims 46 and 53 are novel over Beringer in the feature of gum material including a gum base in the form of one of plasticised rubber and polymer having added texturizers, anti-tacking against and antioxidants, and further claim 46 is novel in the feature of the particle range of the particulated material.

The Examiner has stated that gum base is present at about 60% in Example 2 of Beringer. Applicants respectfully disagree. In example 2 all constituents are stated by parts by weight. With respect to the middle layer 2 the following parts by weight are disclosed: $1.70 + 0.5 + 0.5 + 0.06 + 0.03 + 0.03 = 2.82$ parts by weight, and with respect to the outer layer 1 the following parts by weight are disclosed: $50.0 + 48.0 + 1.0 = 99.0$ parts by weight, and with respect to outer layer 3 the following arts by weight are disclosed: $50.0 + 48.0 + 1.0 = 99.0$ parts by weight.

And in the Example 1 the following parts by weight are disclosed: $1.75 + 0.5 + 0.06 + 0.03 + 0.03 = 2.37$ parts by weight with respect to the middle layer, and with respect to the outer layer 1 the following parts by weight are disclosed: $99.0 + 1.0 = 100.0$ parts by weight, and with respect to outer layer 3 the following arts by weight are disclosed: $98.0 + 2.0 = 100.0$ parts by weight.

If these parts by weight are taken as they are disclosed then there is 1.75 parts by weight of chicle gum out of a total of 202.37 parts in Example 1. And this corresponds to a chicle content of 0.86% by weight of the tablet. And in Example 2 there is 1.70 parts by weight out of a total of 200.82 parts, corresponding to a chicle gum content out of 0.84% by weight of the tablet.

Although this may seem a low value, this is what is actually mentioned in Example 1 and 2 of Beringer. It is also in conformity with the disclosure in Beringer where the chicle gum is used to create a barrier layer between the outer parts, and only a small thickness is required for a barrier layer of chicle in order to provide the barrier effect.

The specific examples disclosed in Beringer either actually teaches a very low chicle content of less than 1 per cent by weight of the tablet, or they are flawed and inconsistent in the manner of presenting the information as to the contents of the constituents. In the latter case there may be an error of scale in either the middle layer or in the outer layers, or an error in the individual constituents of the middle layer. However, what remains is that there is no enabling disclosure of any actual chicle content of 60% as alleged by the Examiner.

With respect to the claim rejections under 35 U.S.C. 103 based on Beringer in combination with other documents, Applicant respectfully traverse the arguments presented in the Official Action for the following reasons.

As explained above, Beringer has no enabling disclosure. The ordinarily skilled person cannot, on the basis of the disclosure of Beringer, produce a tableted chewing gum sweet first of all because the disclosed content of chicle of less than 1 % is simply too low to produce anything but a barrier layer (which seems to be the actual intention in Beringer), but an actual integral part of chewing gum material is not the result when the examples of Beringer is followed. The

chewing gum will not form an integral part but only a layer interposed between integral parts of pure tablet material.

Cherukuri

Cherukuri et al. (US 4,753,805) is silent on the manufacture of a compressed chewing gum sweet with several integral parts. Cherukuri is only concerned with the compression of a tablet as a single layer tablet. Cherukuri discloses the compression of a tablet having a single integral part. As Beringer is teaching a tablet using only a barrier layer with chewing gum, the disclosure of Cherukuri teaches avoiding several layers and instead making the tablet with only a single integral part. The teaching of Cherukuri is to utilize a chewing gum composition with very low moisture content (col. 2 in lines 54-63). For this purpose the ordinarily skilled person receives the teaching to select a grinding aid of alkali metal, alkaline earth metal phosphates, maltodextrins and mixtures thereof (beginning of col. 3). This teaching is supported by the examples presented in Cherukuri, and they all relate to compressed tablets having a single integral part.

Cherukuri is very specific in the disclosure of the particles of chewing gum used for the compression into the single integral part (the tablet). In Example 1 Cherukuri specifies that the final gum composition is formed into ropes and then ground in a Fitzmill to particles. These particles may be powdered by anti-sticking compounds and possibly flavors, and thereafter they are compressed. The gum particles are not mixed with tablet base particles prior to compression.

Applicants respectfully submit that Beringer and Cherukuri cannot be combined because Beringer only discloses such a small amount of gum material, used as a barrier layer, that the

teaching of Cherukuri of making a chewing gum tablet with a single integral part does not combine with the teaching of Beringer.

Applicants further submit that a combination of the two documents cannot result in the invention claimed in claims 1, 20, 25 and 39 because there is not disclosed the combination of firstly making a first integral part of a compressed mixture of particulated gum base material and particulated tablet base material. In this connection it is worth noting that the tablet base material has to be particulated and not just dusting material. The tablet base material has to form individual compressed particles within the first integral part.

Fisher et al. (US 4,370,350) describes in detail how gum base can be mixed with a bulking agent (a sweetener). This is illustrated in Figs. 1 to 6 and explained in columns 2 and 3. The molten gum base is seen in Fig. 1, and the Figures 2 to 6 illustrate what happens when five portions of sugar are step-wise added to the gum base and mixed into the gum base material. During the mixing sugar has the effect to split up the gum base material into smaller particles, and when the full amount of sugar (5 times 80 parts by weight) has been added to the gum base (100 parts by weight) the particles of intermixed gum base and sugar are covered by a single layered coating of sugar as illustrated in Fig. 6. When four times more sugar than gum base has been mixed into the gum base as disclosed in Fisher it is clearly so that the hatched particles in Fig. 7 are of coherent gum material and not anymore particles of gum base material.

The second paragraph of column 4 in Fisher describes that, if the gum particles are pressed together, the sugar coating breaks apart and the “gum base” coalesce into a continuous, coherent gum base network. In Fig. 8 there is a chewing gum mass.

It should be noted that the illustrations and descriptions mentioned in Fisher only explain how the sugar is mixed into the gum base material. It is not a description of a completed tablet. The actual examples given in Fisher are very specific on this point. In Example 1 (column 4, lines 52-60) it is specifically mentioned that the particles produced (the resultant product) were granulated by conventional methods, like compression followed by grinding and sieving before the actual tablets were produced. This means that the structure illustrated in Fig. 8 is broken up by grinding and then the material is sieved and then the tablets are manufactured in conventional manner.

Fisher specifically repeats "The resultant product was granulated and tableted in conventional manner" in column 5 in lines 21-22 (Example 2) and in lines 44-46 (Example 3); in column 6 in lines 23-24 (Example 5), in lines 43-44 (Example 6), and in lines 60-61 (Example 7); and in column 7 in lines 10-11 (Example 8).

Fisher thus also teaches the compression of a single integral part. If Fisher is combined with Beringer the result of the combination is a tablet having a single integral part, and not a tablet having several integral parts as claimed in the present claimed invention. The teaching of Fisher is furthermore consistent with the teaching of Cherukuri in that the integral part comprising compressed particles should only have particles of a single kind, namely of chewing gum, and not a compressed mixture of particulated gum base material and particulated tablet material.

Information Disclosure Statement

In addition to the prior art cited by the Examiner, Applicant has recently become aware of US 1,267,320 to Fries which is from 1918. In 1918 chewing gum was chicle so the disclosure of Fries is a central layer of chicle provided with a layer of sugar on the top and bottom.

The central gum mass is, however, not a layer compressed of particles. It is chicle mass cut out of a plate of rolled out chicle. There is no disclosure in Fries of a layer of a compressed particulated gum base material and particulated tablet base material.

The present claims sets out to provide the consumer with chewing gum tablets that have superior new and exciting chewing properties, including an initial crunch followed by a normal chewing gum stage (cf. paragraph 0006 of the published patent application).

The sensation of initial crunch is important to the consumer as it brings a feeling of delight when the chewing gum tablet is chewed. During the initial chewing stage, which may be e.g. during the initial 30 seconds of chewing, the crunch is caused by the teeth penetrating into the material of the chewing gum tablet, and more precisely into the compressed particles of tablet base material.

Tablet base material that has been mixed together with gum base material to a coherent mass, which is particulated **to particles of one type only**, is not capable of providing the sensation of crunch.

The consumers are aware of the sensation of crunch from the old type of “candy coated” chewing gums where a punched out chewing gum mass has been coated with a brittle outside coating of sugar. But in connection with compressed chewing gum tablets the sensation of distinct crunch is not known.

According to the present claimed invention crunch is provided in a chewing gum tab-let, which comprises at least two proper integral parts with the following features:

A first part of the tablet ("the first integral part") comprises a compressed mixture of (i) particulated gum base material and (ii) particulated tablet base material.

A second part of the tablet ("the second integral part") comprises compressed particulated tablet base material.

As mentioned above, both the gum part and the tablet part of the claimed product are prepared by compression, e.g. using a tablet press. This type of processing is described in paragraph 0030 et. seq.

Some of the special characteristics of the claimed product are described in paragraphs 0037, 0044 and 0047 in which it is explained that an important property of the claimed chewing gum products is that they are associated with a special mouthfeel in terms of an initial **crunchy** sensation which is followed by a chewy sensation.

The above-mentioned beneficial property is accomplished by the specific combination of the features where the use of **particulated tablet base materials** in the gum part (first integral part) combined with the presence of **a separate tablet part** (second integral part) greatly contributes to this crunch effect. Moreover, the compressing of a mixture of both tablet base particles and gum base particles to form the gum part results in the formation of discrete tablet material domains and gum base material domains in the gum part.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the

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Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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